

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

----- X
PUBLIC PATENT FOUNDATION, INC.,

Plaintiff,

- against -

McNEIL-PPC, Inc.,

Defendant.
----- X

Civil Action No. 09-CV-5471-RJH

ECF Case

**MEMORANDUM IN SUPPORT OF McNEIL'S MOTION TO DISMISS
PURSUANT TO FED. R. CIV. P. 12(b)(1) AND 12(b)(6)**

Steven A. Zalesin
Irena Royzman
Ryan Sirianni
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, New York 10036
Tel: (212) 336-2000
Email: sazalesin@pbwt.com

Of counsel:

Attorneys for Defendant McNeil-PPC, Inc.

Anne Martinson, Esq.
Johnson & Johnson

TABLE OF CONTENTS

	<u>Page(s)</u>
TABLE OF AUTHORITIES	ii
INTRODUCTION	1
FACTS	2
A. The Parties	2
B. McNeil’s Tylenol® 8 Hour and Arthritis Products	3
C. McNeil’s Marking of its Tylenol® 8 Hour and Arthritis Products	5
D. The False Marking Statute	6
E. PubPat’s Complaint	7
I. PUBPAT LACKS STANDING TO BRING THIS ACTION	9
A. The Requirement of Article III Standing	9
B. PubPat Has No Standing in its Own Right	13
C. PubPat Has No Standing as a <i>Qui Tam</i> Plaintiff.....	13
II. PUBPAT’S COMPLAINT FAILS TO STATE A CLAIM FOR RELIEF	14
A. Legal Standard for Pleadings	14
B. PubPat’s Pleading Is Deficient.....	16
III. THE PRODUCTS AT ISSUE ARE NOT UNPATENTED ARTICLES.....	17
CONCLUSION.....	22

TABLE OF AUTHORITIES

CASES	<u>Page(s)</u>
<i>American Med. Sys., Inc., v. Med. Eng'g Corp.</i> , 6 F.3d 1523 (Fed. Cir. 1993).....	20
<i>Amsted Indus. Inc., v. Buckeye Steel Castings Co.</i> , 24 F.3d 178 (Fed. Cir. 1994).....	20
<i>Ansul Co., v. Uniroyal, Inc.</i> , 306 F. Supp. 541 (S.D.N.Y. 1969)	18, 19
<i>Arcadia Machine & Tool Inc., v. Sturm, Ruger & Company, Inc.</i> , 786 F.2d 1124 (Fed. Cir. 1986).....	16
<i>Ashcroft v. Iqbal</i> , 129 S.Ct. 1937 (2009).....	<i>passim</i>
<i>Assoko v. City of New York</i> , 2009 WL 1108745 (S.D.N.Y. April 24, 2009)	14
<i>Bell Atlantic Corp. v. Twombly</i> , 550 U.S. 544 (2007).....	14, 15
<i>Chamilia, LLC v. Pandora Jewellery, LLC</i> , 2007 WL 2781246 (S.D.N.Y. Sept. 24, 2007).....	18
<i>Clontech Labs., Inc., v. Invitrogen Corp.</i> , 406 F.3d 1347 (Fed. Cir. 2005).....	19
<i>Conn. v. Physicians Health Servs. Of Conn., Inc.</i> , 287 F.3d 110 (2nd Cir. 2002).....	10
<i>Continental Finance Co. v. Ledwith</i> , 2009 WL 1748875 (S.D.N.Y. June 22, 2009)	14
<i>D.O.C.C. Inc. v. Spintech Inc.</i> , 1994 WL 872025 (S.D.N.Y. August 15, 1994)	16, 18
<i>Devices for Medicine, Inc., v. Boehl</i> , 822 F.2d 1062 (Fed. Cir. 1987).....	20

<i>Douglas v. Wal-Mart Stores, Inc.</i> , 2005 WL 3234629 (E.D. Pa. Nov. 30, 2005)	17
<i>Exergen Corp. v. Wal-Mart Stores.</i> , 575 F.3d 1312 (Fed. Cir. 2009).....	17
<i>FEC v. Akins</i> , 524 U.S. 11 (1998).....	12
<i>FMC Corp. v. Control Solutions, Inc.</i> , 369 F. Supp. 2d 539 (E.D. Pa. 2005)	18
<i>Forest Group, Inc. v. Bon Tool Co.</i> , 2008 WL 2962206 (S.D. Tex. July 29, 2008).....	10
<i>French v. Foley</i> , 11 F. 801 (S.D.N.Y. 1882).....	19
<i>Juniper Networks v. Shipley</i> , 2009 WL 1381873 (N.D. Cal. May 14, 2009)	17
<i>Keystone Mfg. Co. v. Jaccard Corp.</i> , 394 F. Supp. 2d 543 (W.D.N.Y. 2005)	18, 19
<i>Kor-CT, LLC v. Savvier, Inc.</i> , 344 F. Supp. 2d 847 (D. Conn. 2004).....	18, 19, 20
<i>L. Singer & Sons v. Union Pac. R. Co.</i> , 311 U.S. 295 (1940).....	12
<i>London v. Everett H. Dunbar Corp.</i> , 179 F. 506 (1st Cir. 1910).....	10
<i>Lujan v. Defenders of Wildlife</i> , 504 U.S. 555 (1992).....	9, 13
<i>Mass. Inst. of Tech., v. Abacus Software, Inc.</i> , 2004 WL 5268123 (E.D. Tex. Aug. 4, 2004)	21
<i>Max Impact, LLC, v. Sherwood Group</i> , 2009 WL 2448108 (S.D.N.Y. August 10, 2009)	17
<i>Moore North America, Inc., v. Poser Bus. Forms, Inc.</i> , 2000 WL 1480992 (D. Del. Sept. 29, 2000).....	18

<i>Pequignot v. Solo Cup Co.</i> , 2009 WL 2589158 (E.D. Va. Aug. 25, 2009).....	10, 12
<i>Pequignot v. Solo Cup Co.</i> , 2009 WL 874488 (E.D. Va. Mar. 27, 2009)	11
<i>Perkins v. Lukens Steel Co.</i> , 310 U.S. 113 (1940).....	12
<i>Project Strategies Corp. v. Nat'l Comm. Corp.</i> , 948 F. Supp. 218 (E.D.N.Y. 1996)	19
<i>Proportion-Air, Inc. v. Buzmatics, Inc.</i> , 1995 WL 360549 (Fed. Cir. June 14 1995)	18
<i>Sadler-Cisar, Inc. v. Commercial Sales Network, Inc.</i> , 786 F. Supp. 1287 (N.D. Ohio 1991).....	10
<i>Santa Anita Mfg. Corp., v. Lugash</i> , 369 F.2d 964 (9th Cir. 1967)	19
<i>Stauffer v. Brooks Bros., Inc.</i> , 615 F. Supp. 2d 248 (S.D.N.Y. 2009).....	<i>passim</i>
<i>Steel Co. v. Citizens for a Better Env't</i> , 523 U.S. 83 (1998).....	9, 13
<i>Summers v. Earth Island Inst.</i> , 129 S.Ct. 1142 (2009).....	9
<i>Vermont Agency of National Res. v. United States ex rel. Stevens</i> , 529 U.S. 765 (2000).....	9, 10, 13

STATUTES AND RULES

35 U.S.C. § 287	5, 6, 20
35 U.S.C. § 292	<i>passim</i>
Fed. R. Civ. P. 8.....	1, 14, 16
Fed. R. Civ. P. 9.....	1, 17
Fed. R. Civ. P. 11	7
Fed. R. Civ. P. 12.....	1

Defendant McNeil-PPC, Inc. (“McNeil”) respectfully submits this memorandum of law in support of its motion to dismiss the complaint of Public Patent Foundation, Inc. (“PubPat”) pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6).

INTRODUCTION

This case is one of many actions pending in this and other Districts in which practicing patent attorneys seek to collect a bounty on inventions they did not make, and on products they do not sell. The plaintiff, PubPat, is a company founded by a patent lawyer. PubPat does not produce or sell goods of any kind. It has no relation to McNeil, and does not compete with McNeil in any way.

PubPat alleges that McNeil has violated 35 U.S.C. § 292 – the false patent marking statute – with respect to certain of McNeil’s Tylenol® brand products, and seeks a fine of \$500 for each allegedly mismarked article. But PubPat has no standing to bring suit, either in its own right or as a *qui tam* plaintiff. It has sustained no injury in fact, and does not allege any such injury. Nor does it allege any injury to the United States or the public at large. PubPat’s complaint must be dismissed on this basis alone.

In addition, PubPat has failed to plead facts sufficient to state a claim for false patent marking. As the Supreme Court has recently emphasized, “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949 (2009) (“*Iqbal*”). PubPat’s complaint does little more than track the language of 35 U.S.C. § 292 and is thus deficient under Fed. R. Civ. P. 8 and *Iqbal*. PubPat’s conclusory allegations of false patent marking also fall short of the heightened pleading requirements of Fed. R. Civ. P. 9(b) for claims of fraud.

Moreover, PubPat's complaint fails to state a claim because 35 U.S.C. § 292 is applicable only to "unpatented article[s]." The Tylenol[®] products identified in the complaint were in fact patented in the United States, and at least one of them is covered by U.S. patents that are still in force. In addition, all of the products are protected by a foreign patent that remains in effect. Accordingly, they are not "unpatented articles" within the meaning of the statute. And contrary to the theory of PubPat's complaint, the statute allows a manufacturer to mark a product with a patent that covers the product itself, the method by which it is made, or the apparatus used to make it. McNeil's markings fit comfortably within the statutory framework.

For all of these reasons, PubPat's complaint fails to state a claim and must be dismissed as a matter of law.

FACTS

A. The Parties

McNeil is a member of the Johnson & Johnson family of companies. It manufactures and sells a variety of well-known, over-the-counter ("OTC") healthcare products around the world, including Tylenol[®] acetaminophen products. Tylenol[®] pain reliever was first launched in 1955. Since then, McNeil has introduced numerous products under the Tylenol[®] brand across a variety of pain categories, including arthritis pain, pain with accompanying sleeplessness and upper respiratory conditions. McNeil manufactures and sells the three Tylenol[®] pain reliever products identified in PubPat's complaint: 8 Hour Caplets, Arthritis Pain Caplets and Arthritis Pain Gels.

PubPat is a company founded and run by a practicing patent attorney. PubPat has no relation to McNeil. It makes and sells nothing. It does not compete with McNeil in any way.

The attorneys who control PubPat are among the many patent lawyers who have filed actions under 35 U.S.C. § 292 to cash in on products made and sold by others. PubPat alone has brought at least three other 35 U.S.C. § 292 actions in this District in the past few months. *Public Patent Foundation, Inc. v. Cumberland Packing Corp.*, No. 1:09-cv-04360-MGC (Sweet’N Low[®] brand sweetener); *Public Patent Foundation, Inc. v. Iovate Health Sciences Research Inc.*, No. 1:09-cv-04361-SAS (Xenadrine dietary supplements); *Public Patent Foundation, Inc. v. GlaxoSmithKline Consumer Healthcare, L.P.*, No. 1:09-cv-05881-RMB (Citrucel[®] brand therapy products). PubPat never contacted McNeil about its allegations prior to filing this lawsuit.

B. McNeil’s Tylenol[®] 8 Hour and Arthritis Products

The three Tylenol[®] products identified in PubPat’s complaint – 8 Hour Caplets, Arthritis Pain Caplets and Arthritis Pain Geltabs – share a bi-layer formulation technology developed and patented by McNeil’s scientists. Unlike Regular or Extra Strength Tylenol[®], these three products do not release all of their medication immediately to provide temporary pain relief. Instead, they release acetaminophen over an extended period of time to provide more lasting relief. McNeil scientists discovered that this benefit of sustained relief could be achieved by using a bi-layer formulation where a first drug-containing layer dissolves quickly to provide fast relief, and a second layer releases medicine slowly to provide relief for up to eight hours.

McNeil patented this important technology – including both the formulation itself and the methods used to make it – in the United States and abroad. *See, e.g.*, U.S. Patent Nos. 5,004,613 (“the ‘613 patent”; Ex. 1), 4,820,522 (“the ‘522 patent”; Ex. 2), 4,968,509 (“the ‘509 patent”; Ex. 3); Canadian Patent No. 1,315,202 (“the Canadian patent”; Ex. 4).¹ Some of these

¹ “Ex.” refers to the exhibits attached to the accompanying declaration of Steven A. Zalesin.

patents have recently expired. The '522 and '509 patents expired in July and November 2007, respectively. The '613 patent expired in April 2006. The Canadian patent, a foreign counterpart of the United States patents, is still in force and does not expire until March 2010. The claims of the Canadian patent are identical to those of the '522 patent, so they protect the same subject matter claimed in the '522 patent.

In addition to their novel bi-layer formulation, McNeil's scientists also developed and patented technology specific to Tylenol[®] Geltabs in the United States and abroad. In the United States, they obtained a patent on an acetaminophen-containing formulation with a gelatinous outer coating. *See* U.S. Patent No. 5,658,589 ("the '589 patent") (Ex. 5). The '589 patent issued on August 19, 2007 and does not expire until August 19, 2014.

The claimed formulation in the '589 patent requires the use of a specific inactive ingredient, "hydroxypropylmethyl cellulose." *Id.* According to guidelines published by the U.S. Food and Drug Administration ("FDA"), the established name for "hydroxypropylmethyl cellulose" is "hypromellose." *See* Guidance for Industry: Drug Products Containing Ensulizole, Hypromellose, Meradimate, Octinoxate, and Octisalate – Labeling Enforcement Policy (Ex. 6) at 2. Indeed, since September 1, 2003, drug manufacturers such as McNeil have been *required* to refer to hydroxypropylmethyl cellulose as hypromellose in product labeling. *Id.* at 2-3. Tylenol[®] Geltabs, which include hydroxypropylmethyl cellulose as claimed in the '589 patent, are labeled in accordance with this FDA directive. *See* D.I. 1, Ex. D (listing hypromellose as an inactive ingredient).

In addition to their formulation, McNeil developed and patented methods for coating Tylenol[®] Geltabs. These methods are claimed in U.S. Patent Nos. 5,436,026 ("the '026 patent") (Ex. 7) and 5,679,406 ("the '406 patent") (Ex. 8). The '026 patent also includes claims

to the apparatus that McNeil developed and uses to coat its Geltabs. This apparatus is also protected by another patent. *See* U.S. Patent No. 5,228,916 (“the ‘916 patent”) (Ex. 9). The ‘026, ‘406 and ‘916 patents all remain in force. The ‘026 patent issued on July 25, 1995 and does not expire until at least July 25, 2012. The ‘406 patent issued on October 21, 1997 and remains in effect until at least October 21, 2014. The ‘916 patent issued on July 20, 1993 and does not expire until at least July 20, 2010.

In sum, all of the Tylenol[®] products identified in the complaint were in fact patented in the United States, and at least one of them – Tylenol[®] Geltabs – is covered by a U.S. patent that is still in force. The method and apparatus that McNeil uses to manufacture the Geltabs are also still protected by U.S. patents. Moreover, all of the products are protected by at least one foreign patent that remains in effect.

C. McNeil’s Marking of its Tylenol[®] 8 Hour and Arthritis Products

Patentees are encouraged to mark the patented articles that they sell with the applicable patent in order to put the public on notice of the patent’s existence and to avoid innocent infringement. This incentive comes in the form of 35 U.S.C. § 287 – the patent marking statute – which provides in relevant part as follows:

Patentees, and persons making, offering for sale, or selling within the United States any patented article for or under them, or importing any patented article into the United States, may give notice to the public that the same is patented, either by fixing thereon the word ‘patent’ or the abbreviation ‘pat,’ together with the number of the patent, or when, from the character of the article, this can not be done, by fixing to it, or to the package wherein one or more of them is contained, a label containing a like notice. *In the event of a failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice.*

35 U.S.C. § 287(a) (emphasis added).

In accordance with the statute, McNeil provided notice to the public of the patents applicable to its Tylenol[®] products. McNeil marked its Tylenol[®] products with the bi-layer formulation patents. D.I. 1, Exs. A-C. It also put the public on notice that its Tylenol[®] Geltab product is protected by a patent specific to the Geltab formulation (*i.e.*, the ‘589 patent). *Id.* at Ex. C. Moreover, it marked its Tylenol[®] Geltab products with the patents that cover its manufacture (*i.e.*, the ‘026 and ‘426 patents). *Id.* This provides the public with notice that making Geltab products, or importing into the United States such products that are made in the manner claimed in the applicable patents, may constitute infringement. McNeil also marked the Tylenol[®] Geltabs with a patent that covers the apparatus used to coat the Geltabs (*i.e.*, the ‘916 patent). *Id.* As a result of McNeil’s marking of its Tylenol[®] products, the public is able readily to access and examine McNeil’s patents.

D. The False Marking Statute

The false marking statute has been in existence for decades but, until recently, was largely ignored. The statute purports to give “any person” the right to sue for a violation. It reads in relevant part as follows:

(a) ...Whoever marks upon, or affixes to, or uses in connection with any unpatented article, the word “patent” or any word or number importing the same is patented for the purposes of deceiving the public ... [s]hall be fined not more than \$500 for each such offense.

(b) Any person may sue for the penalty, in which event one-half shall go to the person suing and the other to the use of the United States.

35 U.S.C. § 292.

The essential premise of the recent spate of lawyer-driven actions is that anyone can sue for an alleged infraction, and can share in the statutory penalty of up to \$500 for “each such offense” – a term that plaintiffs invariably equate with every product (*e.g.*, each box of Tylenol®) that includes a purportedly erroneous marking.

E. PubPat’s Complaint

In its complaint, PubPat alleges that McNeil violated 35 U.S.C. § 292(a) by “marking and advertising certain products with patent numbers of expired patents and patents that do not ... cover the marketed product.” Compl. ¶ 2. In particular, PubPat faults McNeil for not promptly removing patents that expired in 2007 or 2006 – the ‘522, ‘509, and ‘613 patents – from Tylenol® 8 Hour Caplets. *Id.* at ¶¶ 14, 17-19. It makes the same allegation as to the ‘509 and ‘613 patents for Tylenol® Arthritis products. *Id.* at ¶¶ 15-16.

In addition, PubPat alleges that Tylenol® Geltabs are marked with four patents – the ‘026, ‘406, ‘916 and ‘589 patents – that, though still in force, do not even “arguably” cover this product. *Id.* at ¶¶ 16, 20-23. This conclusory allegation is not backed up by anything in the complaint, which nowhere addresses the fact that the ‘026, ‘406 and ‘916 patents cover the methods by which the Tylenol® Geltabs are made and the apparatus used to make them. As to the ‘589 patent, PubPat offers only the irrelevant assertion that the “hydroxyethyl cellulose” utilized in Tylenol® Geltabs is not “hydroxypropylmethyl cellulose” as required by the claims of the ‘589 patent. *Id.* at ¶ 23. The complaint altogether ignores the fact that hypromellose, which is the same as the hydroxypropylmethyl cellulose claimed in the patent, is listed on the label and is found in the product. *See* D.I. 1, Ex. D.²

² Had PubPat done the barest of inquiries required under Fed. R. Civ. P. 11, it would have discovered as much. Any internet search or review of the United States Pharmacopeia

In similarly conclusory fashion, PubPat alleges that McNeil's allegedly false marking of its Tylenol[®] products is deliberate. The complaint asserts that McNeil is a "sophisticated company" that "knows, or reasonably should know" the requirements of 35 U.S.C. § 292. Compl. ¶ 24. Apparently on this basis and without any factual support, PubPat alleges that McNeil "marks its Tylenol[®] 8 Hour Caplets products with 'U.S. Patent Nos. 4,820,522, 4,968,509 and 5,004,613' for the purpose of deceiving the public into believing that something contained or embodied in its Tylenol[®] 8 Hour Caplets is covered or protected by each of the listed patents." *Id.* at ¶ 25. It makes the same conclusory allegations as to McNeil's Tylenol[®] Arthritis Pain Caplets and Geltabs. *Id.* at ¶¶ 26-27. PubPat does not identify a single fact in support of its assertion that McNeil marks these products "for the purpose of deceiving the public." *Id.* at ¶¶ 26-27. In the same vein, PubPat alleges without any support that McNeil "had and has no reasonable basis to believe that its use of the false markings was or is proper or otherwise permitted under federal law." *Id.* at ¶ 28.

PubPat also alleges that McNeil "publishes false patent information on its Web site for the purpose of deceiving the public into believing that unpatented Tylenol[®] brand products contain or embody 'patented technology.'" *Id.* at ¶ 35. It does not identify a single fact in support of this assertion. The same is true of PubPat's allegation that McNeil "knows, or reasonably should know, that the patent-related statements on its Web site are false and violate 35 U.S.C. § 292." *Id.* at ¶ 34. The complaint contains similarly unsupported and conclusory allegations concerning McNeil's radio commercials. *Id.* at ¶¶ 37-41.

Notably, PubPat's complaint does not allege that McNeil has harmed or injured it or anyone else. It simply avers that "[e]ach time [McNeil] makes, has made, uses, offers to sell,

monographs immediately reveals that hypromellose and hydroxypropylmethyl cellulose are one and the same. *See e.g.*, Exs. 6, 10-12.

or sells within the United States, or imports into the United States” the Tylenol[®] products at issue in the complaint, and/or promotes or advertises these products, McNeil commits an offense under 35 U.S.C. § 292(a), *id.* at ¶¶ 29-30, and seeks a \$500 penalty for each such “offense.” *Id.* at 12-13. PubPat also seeks up to \$500 for each of McNeil’s statements on its Web site or on the radio that Tylenol[®] products include patented technology. *Id.* at ¶¶ 36, 41.

I. PUBPAT LACKS STANDING TO BRING THIS ACTION

A. The Requirement of Article III Standing

All plaintiffs, including *qui tam* plaintiffs, must satisfy the “irreducible constitutional minimum of standing.” *Vermont Agency of National Res. v. United States ex rel. Stevens*, 529 U.S. 765, 771 (2000) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). Standing includes three requirements. “First and foremost, there must be alleged (and ultimately proved) an ‘injury in fact’ – a harm suffered by plaintiff that is ‘concrete’ and ‘actual or imminent, not ‘conjectural’ or ‘hypothetical.’” *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 103 (1998). “Second, there must be causation – a fairly traceable connection between the plaintiff’s injury and the complained-of conduct of the defendant.” *Id.* “And third, there must be redressability – a likelihood that the requested relief will address the alleged injury.” *Id.* “This triad of injury in fact, causation and redressability constitutes the core of Article III’s case or controversy requirement, and the party invoking federal jurisdiction bears the burden of establishing its existence.” *Id.* at 103-104.

“The first requirement – an injury in fact – is the ‘hard floor of Article III jurisdiction that cannot be removed by statute.’” *Stauffer v. Brooks Bros., Inc.*, 615 F. Supp. 2d 248, 253 (S.D.N.Y. May 14, 2009) (Stein, J.) (quoting *Summers v. Earth Island Inst.*, 129 S.Ct. 1142, 1152 (2009)). “Unlike a traditional plaintiff, a *qui tam* plaintiff commonly suffers no

injury himself.” *Id.* The Supreme Court, however, has explained that a *qui tam* plaintiff has standing to sue for his bounty as an assignee of a government claim as long as the United States has suffered an injury in fact. *Vermont Agency*, 529 U.S. at 773-74 (“[T]he United States’ injury in fact suffices to confer standing on [the *qui tam* plaintiff].”). Thus, “*Vermont Agency* grants an assignee plaintiff standing only insofar as the ‘claim’ deemed to be assigned meets constitutional standing requirements.” *Stauffer*, 615 F. Supp. 2d at 254 (citing *Conn. v. Physicians Health Servs. of Conn., Inc.*, 287 F.3d 110, 117 n.8 (2d Cir. 2002)).

The *Stauffer* case addressed standing to sue in the context of a section 292 claim and is therefore directly on point. In *Stauffer*, a practicing patent attorney brought suit against Brooks Brothers, Inc., a manufacturer of men’s bow ties. Plaintiff alleged that Brooks Brothers falsely marked its bow ties with patents that had expired more than half a century ago, and had done so for the purpose of deceiving the public. The *Stauffer* plaintiff sought the same bounty – \$500 per “offense”³ – that PubPat seeks here. Brooks Brothers moved to dismiss the complaint on a number of grounds, including the plaintiff’s lack of standing. The court dismissed the complaint on that basis and did not reach the others. *Id.* at 251.

Judge Stein first analyzed what injury in fact to the United States was needed to confer standing for a section 292 claim. The court explained that “[b]y its terms, the statute seeks to protect the public not simply from false marking of unpatented articles but instead from false marking that is fraudulent, deceptive, and intentional.” *Id.* at 254 (citations omitted). As a

³ Although plaintiffs invariably attempt to equate \$500 per “offense” with \$500 per “article,” this approach has been rejected time and again. Courts instead have construed the phrase “offense” to refer to each *decision* to affix an erroneous marking – not to each product that has been mistakenly marked. *Pequignot v. Solo Cup. Co.*, 2009 WL 2589158, *11 (E.D. Va. Aug. 25, 2009) (“[A]n ‘offense’ under 35 U.S.C. § 292 is a distinct decision to falsely mark.”); *Forest Group, Inc. v. Bon Tool Co.*, 2008 WL 2962206, *6 (S.D. Tex. July 29, 2008) (“That single decision constitutes a single offense for purposes of calculating damages under § 292.”); *London v. Everett H. Dunbar Corp.*, 179 F. 506, 507 (1st Cir. 1910); *Sadler-Cisar, Inc. v. Commercial Sales Network, Inc.*, 786 F. Supp. 1287, 1296 (N.D. Ohio 1991).

result the court held that “the actionable injury in fact that the government is able to assign would have to be an injury to it or to the public stemming from fraudulent or deceptive false marking.” *Id.*

In contrast to the complaint in this case (which alleges no injury of any kind), “Stauffer’s complaint purport[ed] to allege such an injury to the public and to the United States” *Id.* It asserted that Brooks Brothers “‘wrongfully quelled competition with respect to [] bow tie products thereby causing harm to the economy of the United States’” and that Brooks Brothers “‘benefitted [sic] in at least maintaining their considerable market share’” *Id.* at 254. The court found these “conclusory statements ... insufficient to establish anything more than the sort of ‘conjectural or hypothetical harm’ that the Supreme Court instructs is insufficient.” *Id.* at 255; *see also id.* (“That some competitor might somehow be injured at some point, or that some component of the United States economy might suffer some harm through defendants’ conduct is purely speculative and plainly insufficient to support standing.”). The court thus held that the “complaint fails to allege with any specificity an actual injury to any individual competitor, to the market for bow ties, or to any aspect of the United States economy” and dismissed the action for lack of standing. *Id.*

As part of its analysis, the court considered a recent decision by another district court, *Pequignot v. Solo Cup Co.*, 2009 WL 874488 (E.D. Va. Mar. 27, 2009), on standing in the context of section 292 and rejected its approach. In that case, another practicing patent attorney, Pequignot, sued Solo Cup, a manufacturer of disposable cups and lids, for false patent marking and sought to recover \$500 per plastic lid. Pequignot lacked standing to sue as a traditional plaintiff because “he fail[ed] to allege any actual or imminent injury to himself.” *Pequignot*, 2009 WL 874488 at *3. However, the court held that Pequignot had standing to sue as a *qui tam*

plaintiff as an assignee of the government's "sovereign" interest in seeing its laws enforced. *Id.* at *8 n.15.⁴ The court reached this conclusion even though it found no proprietary injury to the United States, and that "the injury to the United States is *only* to its sovereignty." *Id.* at 11 (emphasis added).

The court in *Stauffer* rejected this analysis. *Stauffer*, 615 F. Supp. 2d at 254 n.5. First, it explained that even assuming that a violation of the United States' sovereign interest in law enforcement could be assignable and potentially vindicated by a *qui tam* action, there is no harm to this interest "absent an alleged injury in the form of deception to the public." *Id.* In addition, the court found it unlikely that "the Government's interest in seeing its laws enforced could alone be an assignable, concrete injury in fact sufficient to establish a *qui tam* plaintiff's standing." *Id.* (citing *FEC v. Akins*, 524 U.S. 11, 24 (1998)). As the court explained, "[a]n 'abstract' harm such as 'injury to the interest in seeking that the law is obeyed ... deprives the case of the concrete specificity' necessary for standing." *Id.* (quoting *FEC*, 524 U.S. at 24); *see also L. Singer & Sons v. Union Pac. R. Co.*, 311 U.S. 295, 303 (1940) (harm to "the common concern for obedience to law" is not sufficient for standing); *Perkins v. Lukens Steel Co.*, 310 U.S. 113, 126 (1940) (plaintiffs lacked standing because they failed to show an injury to "a particular right of their own, as distinguished from the public's interest in the administration of the law").

In short, to establish standing in a section 292 action such as this, a plaintiff must plead and eventually prove an actual or imminent injury to himself or to the public as a result of deceptive false marking. *Stauffer*, 615 F. Supp. 2d at 255.

⁴ *Pequignot* has recently been decided in favor of the defendant on summary judgment, on the grounds that there was no evidence of a deceptive intent. *Pequignot*, 2009 WL 2589158 at **6-8.

B. PubPat Has No Standing in its Own Right

PubPat’s complaint does not, and cannot, allege that PubPat itself has suffered an injury in fact. Though PubPat has a financial interest (the sought-after bounty) in the outcome of this action, “the same might be said of someone who has placed a wager upon the outcome.” *Vermont Agency*, 529 U.S. at 772. “An interest unrelated to the injury in fact is insufficient to give a plaintiff standing.” *Id.* Simply put, “an interest that is merely a ‘byproduct’ of the suit itself cannot give rise to a cognizable injury in fact for Article III standing purposes.” *Id.* at 773; *see also Steel*, 523 U.S. at 107 (“[A] plaintiff cannot achieve standing to litigate a substantive issue by bringing suit for the cost of bringing suit.”)

Because PubPat has not alleged and cannot demonstrate an injury in fact, it has no standing to sue in its own right.

C. PubPat Has No Standing as a *Qui Tam* Plaintiff

PubPat also has no standing to sue as a *qui tam* plaintiff. Its complaint does not allege an injury to the United States or any harm to the public. It merely parrots the language of section 292 and makes the conclusory allegation that McNeil has falsely marked its Tylenol[®] products “for purposes of deceiving the public.” Compl. ¶¶ 25-27. PubPat does not allege that any person was deceived, or that any harm or injury occurred as a result of the allegedly fraudulent marking. PubPat does not even allege a speculative or hypothetical harm, much less the “actual or imminent” injury that is required to establish standing. *Lujan*, 504 U.S. at 564.

In short, just as the plaintiff in *Stauffer*, “[PubPat] has failed to allege that defendants’ conduct has caused an actual or imminent injury in fact to competition, to the United States economy, or to the public that could be assigned to [it] as a *qui tam* plaintiff or be

vindicated through the litigation.” 615 F. Supp. 2d at 255. It “therefore lacks standing to proceed.” *Id.*

II. PUBPAT’S COMPLAINT FAILS TO STATE A CLAIM FOR RELIEF

A. Legal Standard for Pleadings

The Supreme Court has recently affirmed that the pleading standard it set forth in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), provides the governing rule in “all civil actions and proceedings in the United States district courts.” *Iqbal*, 129 S.Ct. at 1953. To survive a motion to dismiss, a pleading “must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Iqbal*, 129 S.Ct. at 1949 (quoting *Twombly*, 550 U.S. at 570); *see also Continental Finance Co. v. Ledwith*, 2009 WL 1748875, *2 (S.D.N.Y. June 22, 2009); *Assoko v. City of New York*, 2009 WL 1108745, *2 (S.D.N.Y. April 24, 2009) (Holwell, J.).

In *Twombly*, the Court addressed a complaint that alleged that defendants had “‘entered into a contract, combination or conspiracy to prevent competitive entry into their ... markets and have agreed not to compete with one another’” *Twombly*, 550 U.S. at 551. These allegations closely mirrored the elements of the asserted cause of action, which required a “‘contract, combination ..., or conspiracy, in restraint of trade or commerce.’” *Id.* at 548 (alteration in original). The Court held that the complaint failed to state a claim because the “obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Id.* at 555 (citation omitted). Because the plaintiffs had not “nudged their claims across the line from conceivable to plausible,” their complaint was dismissed as deficient under Fed R. Civ. P. 8. *Id.* at 570.

Iqbal involved a claim that the defendants had denied plaintiff his constitutional rights and engaged in invidious discrimination. Plaintiff alleged that defendants “‘knew of, condoned, and willfully and maliciously agreed to subject [him]’ to harsh conditions of confinement ‘as a matter of policy, solely on account of [his] religion, race, and/or national origin and for no legitimate penological interest.’” *Iqbal*, 129 S.Ct. at 1951. The Court found these bare assertions insufficient:

[Plaintiff’s] complaint does not contain any factual allegation sufficient to plausibly suggest [defendant’s] discriminatory state of mind. His pleadings thus do not meet the standard necessary to comply with Rule 8.

Id. at 1952.

The Court explained that a complaint does not suffice “if it tenders ‘naked assertion[s]’ devoid of ‘further factual enhancement,’” and that a claim only has “facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” 129 S.Ct. at 1949 (quoting *Twombly*, 550 U.S. at 557). The Court made clear that “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Id.*; *see also id.* (“the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions.”). “While legal conclusions can provide the framework for a complaint, they must be supported by factual allegations.” *Id.* at 1950 (emphasis added). The Court concluded that plaintiff’s allegations failed to state a claim because they were no more than “bare assertions ...[that] amount to nothing more than a ‘formulaic recitations of the elements’ of a constitutional discrimination claim” *Id.* at 1951 (citations omitted).

B. PubPat's Pleading Is Deficient

PubPat's complaint ignores the Supreme Court's recent decisions on Rule 8 pleading requirements, and alleges violations of section 292 without the facts necessary to establish a plausible claim. An intent to deceive the public is a critical element of any 35 U.S.C. § 292 claim. As the Federal Circuit made clear, "there can be no violation of § 292 absent an evidentiary showing that the false marking or mismarking was 'for the purpose of deceiving the public.'" *Arcadia Machine & Tool Inc., v. Sturm, Ruger & Company, Inc.*, 786 F.2d 1124, 1125 (Fed. Cir. 1986); *see also D.O.C.C. Inc. v. Spintech Inc.*, 1994 WL 872025, *17 (S.D.N.Y. August 15, 1994) (holding that "section 292 carries a heavy scienter requirement" and that a § 292 claim is not actionable without proof of deceptive intent). PubPat, however, pleads no facts in support of its allegation of deceptive intent.

Instead of setting forth sufficient facts, PubPat's complaint makes conclusory allegations that McNeil "knows, or reasonably should know, that the patent-related statements ... are false and violate 35 U.S.C. § 292." Compl. ¶ 34; *see also id.* at ¶¶ 28, 38. The closest PubPat comes to providing a factual predicate is the assertion that McNeil is "a sophisticated company" that "regularly litigates patent-infringement and false advertising cases" *Id.* at ¶ 24. On this razor-thin basis, and tracking verbatim the language of the statute, PubPat draws the conclusion that McNeil has acted "for the purpose of deceiving the public." *Id.* at ¶¶ 25-27, 35, 40.

These bare-bones assertions – many of which are alleged "upon information and belief" (*see id.* at ¶¶ 25-27, 35, 40) – are precisely the sort that the Supreme Court has deemed unacceptable. PubPat's allegations "amount to nothing more than a 'formulaic recitation of the elements'" *Iqbal*, 129 S.Ct. at 1951. The "complaint does not contain any factual allegation

sufficient to plausibly suggest ... [a deceptive] state of mind.” *Id.* at 1952. Such pleadings “do not meet the standard necessary to comply with Rule 8” and should be dismissed. *Id.*; *see also Douglas v. Wal-Mart Stores, Inc.*, 2005 WL 3234629, *7 (E.D. Pa. Nov. 30, 2005) (dismissing a counterclaim for failure to state a claim under § 292 where an intent to deceive the public was premised on nothing more than “experience[] in intellectual property litigation”); *Max Impact, LLC, v. Sherwood Group*, 2009 WL 2448108, *1 (S.D.N.Y. August 10, 2009) (holding that a counterclaim for false patent marking under § 292 could not “withstand a 12(b)(6) motion to dismiss” where “[n]othing in the allegations sufficiently suggests that [the patentee] acted with a deceptive purpose in marking its [product] as patented.”).

Moreover, a claim under the “false marking statute is a fraud based claim, which is subject to the pleading requirements of Federal Rule of Civil Procedure 9(b).” *Juniper Networks v. Shipley*, 2009 WL 1381873, *4 (N.D. Cal. May 14, 2009). In *Juniper Networks*, the court dismissed plaintiff’s complaint under section 292 for failing to comply with the requirements of Rule 9(b). *Id.* The court found that plaintiff’s “conclusory allegations that [defendant] ‘knew’ his reference to the patents was ‘false’ are [] insufficient to plead an intent to deceive under section 292(a).” *Id.* PubPat’s nearly identical allegations here are likewise insufficient, and its complaint must be dismissed. *See also Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009) (“[a]lthough ‘knowledge’ and ‘intent’ may be averred generally [under Rule 9(b)], [Federal Circuit] precedent, like that of several regional circuits, requires that the pleadings allege sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind.”).

III. THE PRODUCTS AT ISSUE ARE NOT UNPATENTED ARTICLES

PubPat's complaint fails to state a claim for an additional reason: the false marking statute is applicable only to "unpatented article[s]." 35 U.S.C. § 292(a). All of the Tylenol[®] products identified in the complaint were in fact patented in the United States, and at least one of them – Tylenol[®] Gels – is covered by a U.S. patent that is still in force. Moreover, all of the products at issue are protected by a foreign patent that remains in effect. Accordingly, they are not "unpatented article[s]" within the meaning of the statute.

By its terms, the false marking statute is applicable only to "unpatented article[s]." 35 U.S.C. § 292(a). Although section 292 does not define "unpatented article," the statute is "penal in nature and must be strictly construed." *Kor-CT, LLC v. Savvier, Inc.*, 344 F. Supp. 2d 847, 857 (D. Conn. 2004); *see also Proportion-Air, Inc. v. Buzmatics, Inc.*, 1995 WL 360549, *3 (Fed. Cir. June 14 1995) (same); *Chamilia, LLC v. Pandora Jewellery, LLC*, 2007 WL 2781246, *10 (S.D.N.Y. Sept. 24, 2007) (same); *Keystone Mfg. Co. v. Jaccard Corp.*, 394 F. Supp. 2d 543, 565-66 (W.D.N.Y. 2005) (same); *D.O.C.C.*, 1994 WL 872025 at *17 ("Due to its penal nature, section 292 ... is narrowly construed.").

Strictly construed, products that "were covered" by one or more patents are not "unpatented products," and the statute, by its terms is not applicable." *Ansul Co., v. Uniroyal, Inc.*, 306 F. Supp. 541, 565-66 (S.D.N.Y. 1969), *rev'd in part on other grounds*, 448 F.2d 872 (2d Cir. 1971); *see FMC Corp. v. Control Solutions, Inc.*, 369 F. Supp. 2d 539, 584 (E.D. Pa. 2005) ("FMC's patent ... expired in 1997. The Court finds no reason why FMC may not display its patent number to inform the public of where to acquire the informational and teaching *quid pro quo* that underlie the granting of patent protection"). By the same token, "[c]ourts have consistently construed 35 U.S.C. § 292 as not being violated by a patentee who marks a patented article with more patents than actually cover an item." *Moore North America, Inc., v. Poser Bus.*

Forms, Inc., 2000 WL 1480992, *2 n.2 (D. Del. Sept. 29, 2000); *see also Ansul*, 306 F. Supp. at 565-66 (dismissing complaint where two of four patents included in marking did not cover product); *Santa Anita Mfg. Corp., v. Lugash*, 369 F.2d 964, 968 (9th Cir. 1967); *French v. Foley*, 11 F. 801, 805-06 (S.D.N.Y. 1882).⁵

Moreover, in determining whether an article is “unpatented,” courts consider both U.S. and foreign patents. Every court that has addressed the issue has found that articles protected by foreign patents are not “unpatented article[s]” within the meaning of the statute. In *Kor-CT*, for instance, the defendant had five foreign patents but no U.S. patent. 344 F. Supp. 2d at 857. The court found this to be of no moment, holding that “the statute only prohibits the marking of articles that are not subject to *either foreign or domestic* patent protection.” *Id.* (emphasis added). Because the product at issue was “covered by foreign patents,” it was “not ... an unpatented article within the meaning of 35 U.S.C. § 292.” *Id.* at 858; *see also Project Strategies Corp. v. Nat’l Comm. Corp.*, 948 F. Supp. 218, 226-27 (E.D.N.Y. 1996), *aff’d*, 168 F.3d 1320 (Fed. Cir. 1998) (holding that § 292 was not violated due to the existence of a foreign patent); *Keystone*, 394 F. Supp. 2d at 566 (“Section 292 does not differentiate between U.S. and foreign patents.”).

All of the Tylenol[®] products identified in PubPat’s complaint were (until recently) covered by several U.S. patents, and one of them (Tylenol[®] Geltabs) still is. Moreover, the products are all covered by a foreign patent still in force. Accordingly, they are not “unpatented

⁵ In *Clontech Labs., Inc., v. Invitrogen Corp.*, 406 F.3d 1347, 1351 (Fed. Cir. 2005), the Federal Circuit stated in passing that the phrase “‘unpatented article’ in the statute means that the article in question is not covered by at least one claim of each patent with which the article is marked.” *Clontech*, however, did *not* involve a product that indisputably is (or was) patented. The Federal Circuit has yet to address that issue.

article[s]” within the meaning of the statute. PubPat’s complaint should be dismissed on this basis as well. *Ansul*, 306 F. Supp. at 565-66.

For the same reasons, the complaint fails to state a claim as to McNeil’s statements on its Web site or on the radio that Tylenol® products include patented technology. All of the Tylenol® products are protected by a foreign patent. The Tylenol® Geltabs are protected by a U.S. patent. There can be no doubt that these products include patented technology. *Kor-CT*, 344 F. Supp. 2d at 857 (products covered by foreign patent are not “unpatented”).

Finally, PubPat has not alleged a viable claim under § 292 with respect to McNeil’s marking of Tylenol® Geltabs with patents that cover the method by which the products are made, and the apparatus used to make them. “The purpose behind the marking statute [35 U.S.C. § 287] is to encourage the patentee to give notice to the public of the patent.” *American Med. Sys., Inc., v. Med. Eng’g Corp.*, 6 F.3d 1523, 1538 (Fed. Cir. 1993); *see also Amsted Indus. Inc., v. Buckeye Steel Castings Co.*, 24 F.3d 178, 185 (Fed. Cir. 1994). Accordingly, “[w]here the patent contains both apparatus and method claims ... to the extent that there is a tangible item to mark by which notice of the asserted method claims can be given, a party is obliged to do so, if it intends to avail itself of the constructive notice provisions of section 287(a).” *American Med. Sys.*, 6 F.3d at 1538-1539.

By marking its products with patents that cover their method of manufacture and the apparatus used to make them, McNeil gives the public – including its competitors – notice of the existence of these patents. Such information helps the recipient decide whether it may market a competing product produced by the same method or apparatus, or must find another means of manufacture that does not infringe. That is precisely how the marking statute is

supposed to work. *See Devices for Medicine, Inc., v. Boehl*, 822 F.2d 1062, 1066 (Fed. Cir. 1987) (patentee could not obtain damages for infringement of a method patent after “[h]aving sold the product unmarked”); *Mass. Inst. of Tech., v. Abacus Software, Inc.*, 2004 WL 5268123, *21 (E.D. Tex. Aug. 4, 2004) (“in the balance struck by §§ 287(a) and 292, there is a clear weight on the side of marking, even if it results in a notice that includes patents that may not actually cover the vended article.”). Such conduct cannot, as a matter of law, give rise to a claim of false patent marking.

CONCLUSION

For the reasons set forth above, McNeil respectfully requests that the Court dismiss PubPat's complaint.

Dated: October 5, 2009

Respectfully submitted,

By: /s/ Steven A. Zalesin

Steven A. Zalesin
Irena Royzman
Ryan Sirianni
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, New York 10036
Tel: (212) 336-2000
Email: sazalesin@pbwt.com

Attorneys for Defendant McNeil-PPC, Inc.

Of counsel:

Anne Martinson, Esq.
Johnson & Johnson